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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,449	03/10/2004	Thomas A. Osborne	1-37213	4445

42715 7590 05/07/2007

DUNLAP, CODDING & ROGERS, P.C.
P.O. BOX 16370
OKLAHOMA CITY, OK 73113

EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	
MAIL DATE	**DELIVERY MODE**
05/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10797449	3/10/04	OSBORNE ET AL.	1-37213

DUNLAP, CODDING & ROGERS, P.C.
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EXAMINER
Bruce Snow

ART UNIT	PAPER
3738	20070502

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

In view of the papers filed July 23, 2004 (see paper scan date September 1, 2004), it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of an inventor, Ram H. Paul.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Snow whose telephone number is 571 272-4759. The examiner can normally be reached on Monday-Friday from 8:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BRUCE SNOW
PRIMARY EXAMINER

Office Action Summary	Application No.	Applicant(s)	
	10/797,449	OSBORNE ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *12 and 16-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☒ Other: Attachments 1-2

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-11 and 13-15 have been considered but are moot in view of the new ground(s) of rejection.

Applicants have argued that Duran et al. (US 7,125,418 B2) does not disclose an opening that permits a controlled amount of fluid flow to pass through the medical device in a second direction. The examiner disagrees for several reasons. First, the ability for the opening to allow fluid to pass is functional language and is dependent upon the size of the vessel in which the device is placed. When placed in a large vessel (which Duran's device is capable of doing), the leaflets will not make a complete seal with the vessel wall and thus permit some blood therethrough. Thus, Duran's device is *capable* of allowing some blood through, this is dependent upon the use, whether the device is placed in a large or small vessel, *it is capable of being placed in a large vessel in which fluid would pass therethrough.* Second, as seen in figure 9 for example, blood is capable of traveling *through* the device, between the stent and leaflets, into the branch vessel, see attachment 1. Third, applicant has not defined the term "through" and therefore it is given its broadest plain meaning, for instance: between or among the individual members or parts, within the limits of, extending from one surface to another, see www.dictionary.com, and Merriam-Webster's collegiate Dictionary, 10th edition, 2001. Therefore, since blood travels along parts of the medical implant (see attachment 1, fig.11A), it thus is considered to travel *through* the implant.

Applicants has also argued that Moll et al. (US 6,287,334 B1) does not disclose an opening that permits a controlled amount of fluid flow to pass through the medical device in a

second direction. The examiner disagrees for several reasons. First, the ability for the opening to allow fluid to pass is functional language and is dependent upon the size of the vessel in which the device is placed. When placed in a large vessel (which Moll's device is capable of doing), the leaflets will not make a complete seal with the vessel wall or one another and thus permit some blood therethrough. Thus, Moll's device is *capable* of allowing some blood through, this is dependent upon the use, whether the device is placed in a large or small vessel, *it is capable of being placed in a large vessel in which fluid would pass therethrough*. See figure 1, wherein even in the closed configuration, an opening is present between pockets 16, which some blood would inherently pass, see attachment 2. Second, prior to the leaflets being in the completely closed configuration, some small amount of blood will inherently escape therethrough, see col.2, lines 55-57. Third, applicant has not defined the term "through" and therefore it is given its broadest plain meaning, for instance: between or among the individual members or parts, within the limits of, extending from one surface to another, see www.dictionary.com, and Merriam-Webster's collegiate Dictionary, 10th edition, 2001. Therefore, since blood travels along parts of the medical implant (into pockets 16, from the proximal to the distal end and then back), it thus is considered to travel *through* the implant.

Claim Rejections - 35 USC § 101

Claims 9-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claiming a comparison to a portion of the body is non-statutory subject matter. Claims 9-11 each recite, "opening is less than ..of the cross-sectional area of said body vessel". Applicant has compared the device directly to the body vessel. Therefore, the dimensions have been claimed in relation to a body part. Therefore, the size of the body part has

been indirectly claimed. It is suggested to change the above to recite, --the opening is sized (or configured) to be less than ...of a cross-sectional area of said body vessel--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7-9, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Duran et al. (US 7,125,418 B2, cited previously). Duran discloses a medical device (fig.6, 8, 11A, 11B) comprising a radially expandable support frame (stent 27+28+23; OR 17+18+23), at least one leaflet (located between commissures 20 in figs.) having a first edge (bottom inflow edge) attached to the support frame (at 17) and a second edge (top outflow edge) free from the frame (at 20a), the leaflet movable from a first position (seen open in figs.7a, 8b, 9) permitting flow in a first direction and a second position (seen in figs.11a, 8c) substantially preventing flow in a second direction, a portion of the frame (28) and second edge (20a) cooperatively defining an opening (seen in figs.11a, 9) that permits a controlled amount of flow in the second direction through the device (see attachment 1). Duran discloses the frame to be same expanding Ni-Ti (col.5, lines 105, 64-68), and the leaflet to be bioremodelable (col.3, lines 36-42, 58-61). Duran discloses the leaflet attaching to the frame by a suture (17, 18), the device comprising two

leaflets (see figs) and the opening to cover less area than the total vessel cross section (seen in fig.11a).

Claims 1, 2, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Moll et al. (US 6,287,334 B1, cited in IDS). Moll discloses a medical device comprising a radially expandable support frame (10), at least one leaflet (12) having a first edge attached to the support frame (along 8) and a second edge free from the frame (free edge of 12, see attachment 2), the leaflet movable from a first position (fig.5) permitting flow in a first direction and a second position (fig.6) substantially preventing flow in a second direction, a portion of the frame (10) and second edge (free edge of 12) cooperatively defining an opening (near 16) that permits a controlled amount of flow in the second direction through the device (a controlled amount fill pocket; col.1 line 62-col.2 line 7). Moll discloses the frame to be same expanding (col.2, lines 19-26; fig.3, 4). Moll discloses the leaflet (12) attaching to the frame (10) by a suture (stitching seen in fig.1), the device comprising two leaflets and the opening to cover less area than the total vessel cross section.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 6, 10, 11, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duran et al. (US 7,125,418 B2). Referring to claims 5, 6, 14, and 15, Duran discloses a

medical device comprising tissue valve leaflets (col.3, lines 36-42, 58-61), however does not specifically disclose ECM or submucosa (particular types of tissue). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed materials for the leaflets, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Referring to claims 10 and 11, Duran has shown an opening formed between the frame and leaflet edge when in the closed position, opening only a portion of the vessel cross-section (see fig.11a for example), however is silent to mention an exact percentage of openage. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the percent open area claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 3-6, 10, 11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. (US 6,287,334 B1). Referring to claims 3-6 and 13-15, Moll discloses a medical device (fig.1) having all the structural features claimed (see above), however does not disclose the exact materials claimed for the frame and leaflet. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed materials for the leaflets and frame, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Referring to claims 10 and 11, Moll has shown an opening formed between the frame and leaflet edge when in the closed position, opening only a portion of the vessel cross-section (16; fig.1), however is silent to mention an exact percentage of openage. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the percent open area claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER

Attachment #1 (marked up)

FIG. 9

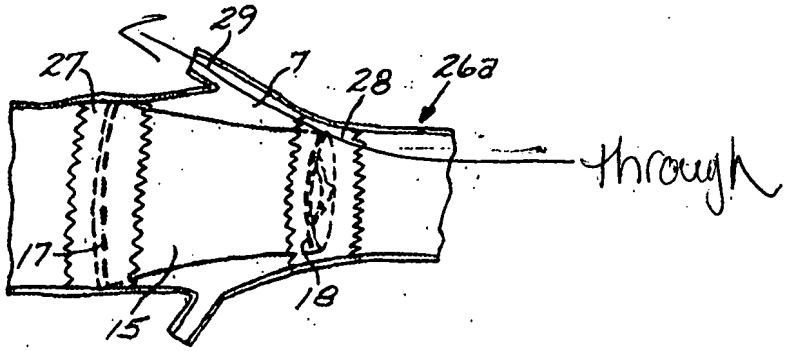


FIG. 10

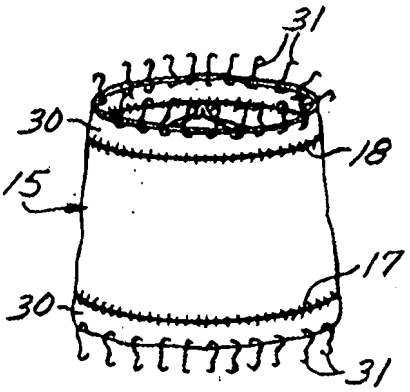


FIG. 11A

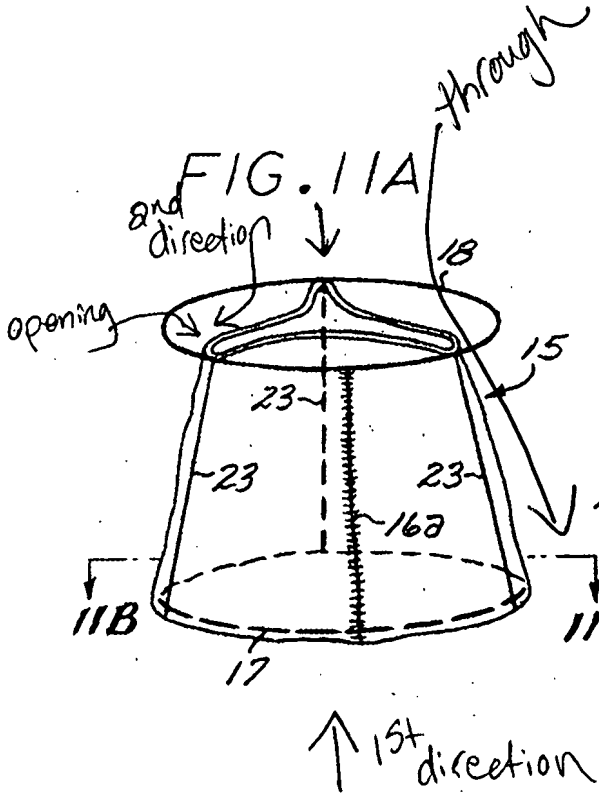
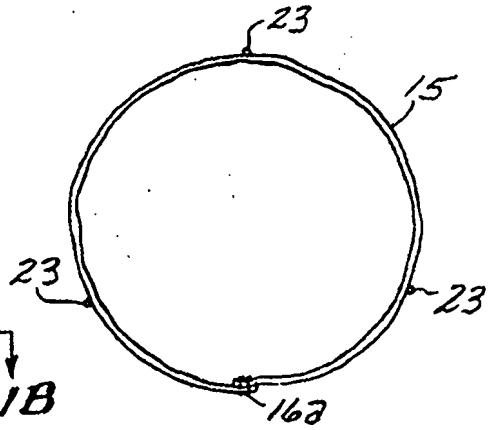


FIG. 11B



Attachment #2 (marked up)

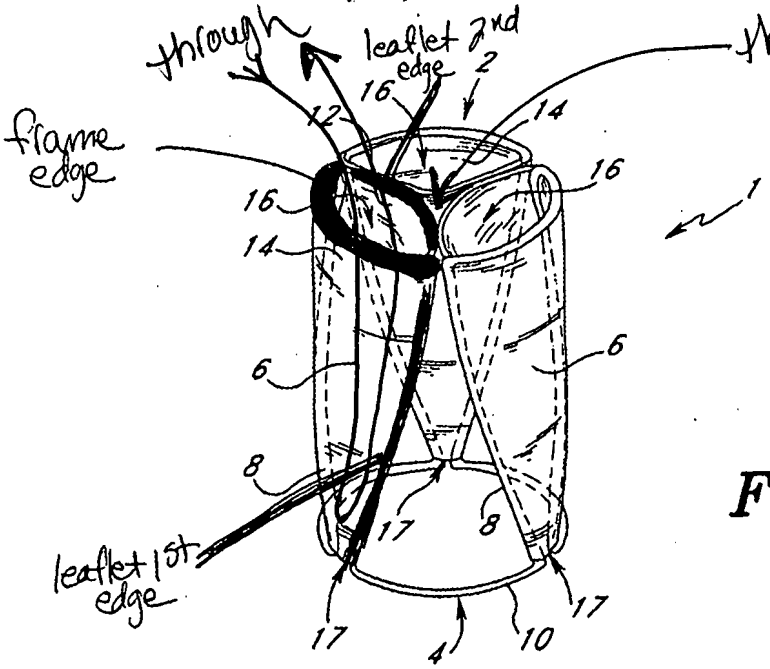


FIG. 1

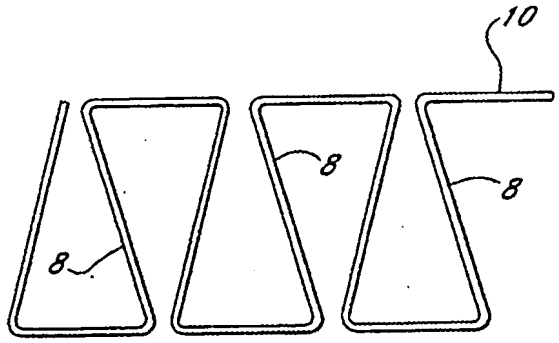


FIG. 2

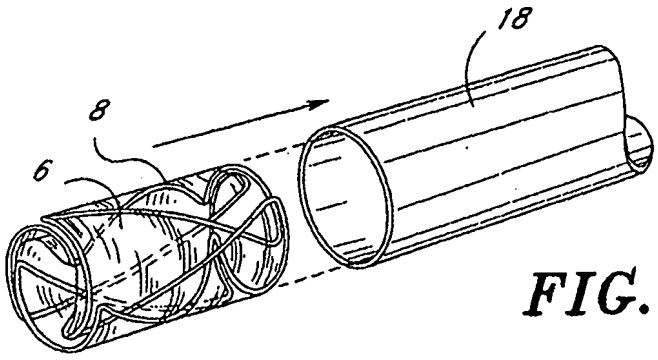


FIG. 3